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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,709	02/10/2004	Alessandra Orlandi	PI3846US2	3334

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EXAMINER	
COPPINS, JANET L	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,709	ORLANDI, ALESSANDRA	
	Examiner	Art Unit	
	Janet L Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/148,434.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-12 pending in the instant application.

Response to Preliminary Amendment

1. Receipt is acknowledged of Applicants' Preliminary Amendment, filed February 10, 2004, which has been reviewed by the Examiner and entered of record in the file. Accordingly, claims 1-8 have been cancelled and new claims 9-12 have been added.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement, filed on February 10, 2004, has been considered by the Examiner. Please refer to Applicant's copy of the 1449 submitted herewith.

Priority

3. This Application is a continuation of U.S. Patent Application Serial No. 10/148,434, filed 29 May 2002 (now allowed) which was filed pursuant to 35 U.S.C. 371 as a United States National Phase Application of International Application No. PCT/EP00/12335, filed December 7, 2000, which claims priority to Great Britain Patent Application No. 9929037.1, filed December 8, 1999.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for treating diseases such as headaches, inflammatory and

neuropathic pain, IBS, drug dependency etc., does not reasonably provide enablement for the prophylaxis of said diseases. The term "prophylaxis" includes both treatment and prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention in claims 9 and 11 is a method for the treatment or prophylaxis of diseases such as irritable bowel syndrome and epilepsy. Even if the patient has a genetic predisposition to the selected identified disease states, you are still treating the individual patient, and not preventing. It has not been shown in the specification that the "**prophylaxis**" of such disease is accepted in the art as being predictive of the utility alleged, especially when absent of pharmacological data.

The state of the prior art

The diseases that the instant claimed compound is enabled for treating include neurodegenerative diseases. Although the clinical and neuropathological aspects of these diseases are distinct, their unifying feature is that each disease has a characteristic pattern of

neuronal degeneration in anatomically or functionally related regions. Presently available pharmacological treatments for the neurodegenerative disorders are symptomatic and do not alter the course of or progression of the underlying disease (see Goodman and Gilman's, The Pharmacological Basis of Therapeutics, 10th Edition, page, 549). Therefore, the state of the art is limited to treatment of said diseases and not the "prophylaxis" or prevention of said diseases.

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The predictability or lack thereof in the art

Because of high level of unpredictability associated with **"prevention"** of certain diseases such as epilepsy, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the

contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The specification discloses methods of treating diseases such as inflammatory pain and headache, using the compounds described in the specification. The compounds that are disclosed in the specification, which have data regarding treatment of diseases such as IBS and epilepsy, have no pharmacological data regarding the prevention of said diseases. The specification is short of any data (animal models, *in vitro*, or *in vivo* testing) in regards to the prevention of said diseases. Merely stating that the instant compounds are preventable against, for example epilepsy does not establish usefulness of the invention absent art-recognized correlation between such tests and the ultimate use.

The presence or absence of working examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re Barr* et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The instant specification at most only provide one example for treating diseases such as Alzheimer's'. No examples have been set forth describing the prevention of said diseases.

The quantity of experimentation needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine whether the claimed compounds would prevent the

claimed diseases. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that, "a patent is not a hunting license. It is not a reward for research, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would prevent for example epilepsy by the method encompassed in the instant claims, with no assurance of success.

It is suggested to delete the term "prophylaxis" to overcome the rejection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
September 30, 2004

for Kamal Saeed
Joseph K. McKane,
SPE, Art Unit 1626